NIH CRADA FACT SHEET

NIH scientists should be aware of the following ***FACTS*** before entering into any Cooperative Research and Development Agreement (CRADA), specifically a standard CRADA, Clinical Trial CRADA, or Materials CRADA. The word "CRADA" is generic and includes all three types of agreements.

FACT: A CRADA is a contractual agreement between NIH and the Collaborator whereby the Collaborator has the option to exclusively license inventions that are developed jointly with or independently by NIH scientists;

FACT: CRADA Research Plans and financial information are CONFIDENTIAL and should not be disclosed to anyone outside the collaboration;

FACT: All staff members associated with a CRADA share the responsibilities regarding CRADA confidentiality, particularly in relationship to other research collaborations in which they may be involved and/or employment activities they may be pursuing;

FACT: The materials or funds provided by the Collaborator are to be used ONLY in the CRADA, as identified in the Research Plan, by those under the supervision of the CRADA Principal Investigator and may not be distributed to third parties;

FACT: CRADA Collaborators review all publications/oral presentations related to the Research Plan of the CRADA for CONFIDENTIAL or inventive information prior to any public disclosure (including submission for public disclosure consideration).

NIMH CRADAs
Review and Approval Process

Initiation

Step 1. Principle Investigators (PIs) from both parties jointly develop a Research Plan, using NIH CRADA Subcommittee guidelines and determine the resources needed to accomplish project goals. Next, they submit CRADA Appendix A (the "Research Plan") and CRADA Appendix B (the "Financial & Staffing Contributions of the Parties") to the NIMH Technology Development Coordinator (TDC).

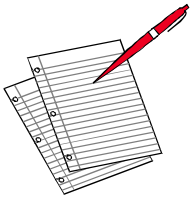
Step 2. Concurrently, the non-NIMH collaborating party reviews the NIH/NIMH CRADA boilerplate and contacts the NIMH Office of Technology Transfer with any questions or areas of negotiation. Proposed boilerplate amendments, after their negotiation with the Office, are attached to the final CRADA as Appendix C.

Step 3. The NIMH PI submits NIH/NIMH-specific papers (that is, the CRADA Clearance form, Conflict of Interest/Fair Access Survey statement, resource impact memo, etc.) to the NIMH Technology Transfer Office.

Reviews

- ☑ NIMH/DIRP Technology Advisory Committee
- ☑ NIH CRADA Subcommittee (The NIMH TDC submits the final negotiated CRADA package to the NIH CRADA Subcommittee for review.)
- ☑ After discussion of any Subcommittee recommendations with the Collaborator, the CRADA is revised and resubmitted to the CRADA Subcommittee Chairman for signature.

Internal Approvals (that is, required signatures on the NIH CRADA Clearance Form)



- ☑ Principle investigator, NIMH
- ☑ Lab/Branch Chief
- ☑ NIMH Technology Development Coordinator (TDC)
- ☑ Scientific Director, NIMH Intramural Research Program
- ☑ Office of General Counsel (OGC)*
- ☑ NIH Office of Technology Transfer (OTT)*
- ☑ CRADA Subcommittee Chairperson*
- ☑ NIH Deputy Director for Intramural Research

*Reviews the CRADA for submission to the CRADA Subcommittee and approves any final changes made.

Signatures on the CRADA

- ☑ Director, NIMH
- ☑ Authorized Party for Collaborator(s)

Principal Investigators' CRADA Checklist

For your convenience, check off each item below. If possible, please submit Appendixes A and C to the NIMH Technology Transfer Office in either (a) clean copy suitable for scanning or (b) ASCII text format for the personal computer.

☐ **CRADA Clearance form**

- ☐ Put "upon signature" into effective date box (unless a specific date is appropriate)
- ☐ Fill in everything (except CRADA #); put "N/A" or "0" when box is not applicable
- ☐ Make sure that the person-year box totals match what is said in Appendix B
- ☐ Note that the "$" box refers *only* to money actually transferred to NIH

☐ **Appendix A (Research Plan)**

- ☐ Make sure that the Research Plan spells out clearly the intellectual, as well as material contribution(s), of the other party(ies)

- ☐ Be certain that the Research Plan scope is explicit and narrowly defined. Specific drugs or disease states under investigation, for example, must be clearly identified to be considered part of the CRADA research. Vague or ambiguous statements, such as "a variety of drugs" or "various disease entities" are not acceptable. Note: Basic research CRADAs and clinical trials using the basic research results therefrom require using two separate CRADA vehicles; CRADAs involving patient care call for additional boilerplate language beyond basic research CRADAs.

- ☐ Assure that Appendix A has followed exactly the format found in the "Supplement to Appendix A" guidelines (include a listing of all CRADAs, related MTAs, and patent applications, etc.)

- ☐ Number the pages of Appendix A

☐ **Appendix B**

- ☐ Using the template (Sample Appendix B) supplied by the NIMH Technology Transfer Office, list all financial and staffing contributions to which the parties have agreed; list NIMH and each collaborator separately.
- ☐ List types of positions (rather than names of staff) and provide the "%" of time each will work on the CRADA project. Give a "$" estimate of the total salaries based on the "%" of time spent on the CRADA research.
- ☐ Please note any provision of travel to be paid by the collaborator. The possibility of travel should be addressed even if the collaborator does not believe initially that travel will occur. The reason to address this is because obtaining permission later on for sponsored travel is exceptionally difficult where it is not expressly stated in Appendix B. (The language can be changed to make it an option.)

Appendix C

- ☐ The collaborator should attach any typewritten modifications to the NIH/NIMH legal boilerplate on a separate page or pages comprising Appendix C in a format that clearly shows all deletions and insertions

Cover sheets

- ☐ Fill in front cover page and the cover to Appendix A

Signature page

- ☐ Fill in addresses for notices

Miscellaneous

- ☐ Assure that the company sends appropriate (**animal or human subjects**) assurance forms/letters
- ☐ Complete as required for all NIMH Principal Investigators the NIH **Conflict of Interest/Fair Access Survey** form
- ☐ Submit an **Impact of Resources memo** to the Intramural Research Programs (IRP) Scientific Director (to be signed by Lab/Branch Chief)
- ☐ Mark your calendar as appropriate for a CRADA Subcommittee meeting to present your CRADA to the Subcommittee